

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF  
TIMMINS ET AL.

Art Unit: 1615  
Examiner: J. Spear

APPLICATION NO: 09/398,107

FILED: SEPTEMBER 16, 1999

FOR: BIPHASIC CONTROLLED RELEASE DELIVERY SYSTEM FOR  
HIGH SOLUBILITY PHARMACEUTICALS AND METHOD

Box AF  
Assistant Commissioner for Patents  
Washington, D.C. 20231

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SUPPLEMENTAL AMENDMENT AFTER FINAL REJECTION

Sir:

As discussed with Examiner Spear on March 19, 2002, and further in response to the Final Rejection mailed January 16, 2002, applicants request that this application be amended as follows:

In the Specification:

Page 25, line 37, please change " \_\_\_\_\_ " to --5,563,440--.

In the Claims:

Please amend claims 1, 4, 7, 20, 26, 29, 43, 54, 59 and 62 to read as follows.

--1. (Twice Amended) A pharmaceutical formulation comprising (1) an inner solid particulate phase, and (2) an outer solid continuous phase in which particles of the inner solid particulate phase are dispersed and embedded, the particles of the inner solid particulate phase comprising (a) a pharmaceutical having a high water solubility selected from metformin or a pharmaceutically acceptable salt thereof; and (b) an extended release material, and the outer solid continuous phase comprising an extended release material, wherein the total extended release material content in

Approved  
For Entry  
H-H-OV  
J. Spear

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